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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,078	07/25/2001	William F. Wade	PM	7302

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

10)

Office Action Summary	Application No.	Applicant(s)	
	09/720,078	WADE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group III (claims 1, 2, and 5-17) drawn to a method of enhancing a humoral or CD4 Th1 (DTH, cell-mediated) immune response by administering an antibody-antigen conjugate wherein the antibody binds a dendritic cell antigen and tumor or cancer antigens and an breast cancer antigen with traverse is acknowledged.

Applicant traverses the requirement that a specific class and type of antigen be elected. Applicant notes that the ordinary artisan would reasonably expect that results obtained by the invention with experimental antigens such as hen egg lysozyme and avidin are also predictive of results expected with the invention with regard to antigens associated with any of a large number of pathologies.

Given applicant's admission that the specific class and type of antigen are obvious variants over one another, the species of classes and types of antigens are held obvious in view of one another in the instant application.

Given applicant's admission that the species of classes and types of antigens are held obvious in view of one another in the instant application, claims 8-11 and 16-17 have as they read on the non-elected antigens have been rejoined to the elected species in the instant application.

Claims 1, 2 and 5-17 are under consideration in the instant application as they read on the elected invention as indicated above.

Claims 1-30 as they read on the non-elected inventions and species are withdrawn from consideration in the instant application.

2. The filing date of claims 1, 2, 5, 8 and 11-15 is deemed to be the filing date of priority application USSN 60/090,849, filed 6/26/98.

It appears that the filing date of the instant claims drawn to "aged or immunocompromised individuals, human subject fifty years or older (claims 6-7), "toxin" (claim 9), "lung, head and neck, uterine and leukemia" cancer or tumor cells antigens (claim 10) , "protozoan disease" (claim 16), "leishmanin?????, Listerine?????, leprosy or tuberculosis infection" (claim 17) is deemed to be the filing date of priority application PCT/US99/12825, filed 6/25/99.

If applicant desires priority prior to 6/25/99 for claims 6, 7, 9, 10 16 and 17; applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

3. No Information Disclosure Statement has been filed with this application.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. Claims 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 is indefinite in the recitation of "leishmanin?????" and "Listerine?????" given the ambiguities of such terms.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

Applicant is reminded that both the error and the correction have to obvious to avoid adding new matter.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2 and 5-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Anand et al. (US 6,291,208 B1) and Heath (US 2002/0135722 A1) and further in view of applicant's admission that species of classes and types of antigens are held obvious in view of one another in the instant application.

Anand et al. teach the use of antibody conjugates comprising antibodies that bind antigen presenting cells, including dendritic cells (e.g. column 2, paragraphs 4 and 6), to deliver antigens in order to generate immunogenic compositions to a variety of antigens (e.g. column 7, paragraph 2) (see entire document, including Summary of the Invention and General Description of the Invention). Anand et al. Teach that these is applicable to any antigen which it is desired to target to antigen presenting cells, including antigens derived from viruses, bacteria and tumors (see column 7, paragraph 1)

Heath teaches the co-administration of a CD40 stimulating moiety (e.g. anti-CD40 antibodies) (e.g., see paragraphs 0055, 0061, 0062) and the appropriate antigen, including the use of covalent linkage or co-entrapment as a vaccine (e.g. see paragraphs 0026-0027 and 0029) to a variety of antigens (see entire document, including Summary of the Invention).

In addition to the variety of antigens as well as the general applicability of antigens as taught by Anand et al. and Heath, applicant's election, filed 11/3/03, notes that the ordinary artisan would reasonably expect that results obtained by the invention with experimental antigens such as hen egg lysozyme and avidin are also predictive of results expected with the invention with regard to antigens associated with any of a large number of pathologies. Given applicant's admission that the specific class and type of antigen are obvious variants over one another, the species of classes and types of antigens are held obvious in view of one another in the instant application.

Although Anand is silent about aged or immuno-compromised individuals, the ordinary artisan would have immediately envisaged or would have found it obvious to activate the immune response is such individuals, given the prior art teachings of stimulating immune response to a variety of antigens, including pathogens and tumor associated antigens (e.g. see column 7, paragraph 2 of Anand et al.). Also, it is noted that Anand et al. teach that the quantity to be administered depends on the subject to be treated, including the capacity of the individual's immune-system to synthesize antibodies and to produce a cell-mediated immune response (column 9, paragraph 1).

In addition, Heath teaches that providing anti-CD40 with antigen has an advantage for the vaccination of patient with immune deficiencies (paragraph 0126).

Therefore, it would have obvious for the ordinary artisan to enhance immune responses or vaccinate aged or immunocompromised individuals as well as subjects fifty years or older in order to stimulate immune responses or to vaccinate such individuals to a wide variety of antigens based on need. For example, boosting immune responses to a variety of antigens (e.g. pathogens or tumor antigens) in such individuals was known and practiced at the time the invention was made.

Given the teachings of Heath to provide anti-CD40 with antigen in composition form or as a conjugate (see Summary of the Invention) and the teachings of Anand et al. to provide antigen with anti-antigen presenting cell / dendritic cell antibodies; it would have been obvious to one of ordinary skill in the art to administer the antigen in the context of such antigen-antibody conjugate with the immunostimulatory anti-CD40 antibodies to boost the immune response to a wide variety of desired antigens, including providing both components in the same composition, as taught by Heath (see paragraphs 0026-0027 and 0029).

In addition, the motivation to combine the prior art can arise from the expectation that the prior art elements will perform their expected function to achieve their expected results when combined for their common known purpose. Here, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine both antigen-antibody conjugates for dendritic cells and CD40-specific antibodies to target antigens to the antigen presenting cells of interest, including CD40-expressing antigen presenting cells, as well as to enhance the immunogenicity of said antigens.

Given the teachings of Anand et al. and Heath; the ordinary artisan would have been motivated to target professional antigen presenting cells such as dendritic cells with the combination of antigen-antibody targets and the immunostimulatory agonistic CD40 antibodies to enhance the immune response to a wide variety of antigens. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PHILIP GAMBEL

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February 23, 2004